

1487 '99 SEP -8 A10:22

August 30, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville
MD 20852

Dear Sirs :

Re : Docket Number 98N-1215

We are a small Ontario company manufacturing medical devices, and exporting mostly to the United States.

While we already comply with FDA regulations, the proposed new ruling for Foreign Establishment Registration and Listing would place an undue financial and administrative burden on small companies such as ours.

The requirement to have an identified U.S. agent is impracticable, since we typically change distributors from time to time and may sometimes use multiple agents. We would have difficulty maintaining any one company in that role without incurring considerable cost.

I trust that you will consider the fact that the implementation of the FTA should lessen administrative burdens for Canadian companies, rather than increasing them.

Yours truly,



Norma Thomson,
Vice President.

c.c. Birgit Mattiesen, Canadian Embassy, Washington
Debbie Walker, U.S. Healthcare, Government of Ontario.

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Thomson & Nielsen Electronics Ltd
25E Northside Road,
Nepean ON Canada K2H 8S1

98N-1215

Thomson|Nielsen

25E Northside Road.
Nepean ON Canada
K2H 8S1



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Food & Drug Administration
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USA

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